

rapid lysis of cells, spores, or microorganisms captured on the filter. As a specific example, rapid lysis of spores in a 100 μ l sample was accomplished by applying ultrasound for thirty seconds at a frequency of 47 kHz and an ultrasonic output of 50 watts. Ultrasonic output in the range of 10 to 60 watts is presently preferred. The ultrasonic lysis may be performed with or without the use of lysing reagents, e.g., chaotropes, detergents, salts, and reducing agents. The ultrasonic lysis permits the choice of buffer/resuspension solution related to the post lysis protocol (e.g., buffer that is non-inhibitory to PCR).

[0212] Typically, the ultrasonic transducer will be a separate component from the cartridge and coupled to the cartridge by an operator or machine. Alternatively, the transducer may be located in an external instrument that receives the cartridge for processing. In this embodiment, the transducer is preferably positioned in the instrument such that it presses against a wall of the lysing chamber when the cartridge is inserted into the instrument for processing. In another embodiment, the transducer may be built into the cartridge. In this embodiment, the cartridge includes suitable electrical connectors for connecting the transducer to a power supply. In embodiments in which the transducer is built into the cartridge, the transducer should be prevented from contacting the fluid sample directly, e.g., the transducer should be laminated or separated from the sample by a chamber wall.

[0213] The cartridge **70** may be fabricated using techniques previously described for the cartridge of FIG. **2**. In particular, the cartridge **70** preferably comprises first and second molded plastic parts **78** and **80** which support filter **86**. Filter **86** may optionally be heat sealed to the plastic parts **78** and **80**. The cartridge also includes first and second plastic films **82** and **84** sealed to parts **78** and **80**, respectively. Examples of suitable materials for the plastic parts **78** and **80** and for the films **82** and **84** include, e.g., polycarbonate, polystyrene, polypropylene, polyethylene, acrylic, and commercial polymers. To aid in the transfer of ultrasonic energy to the sample components, it is preferred that films **82** and **84** be relatively thin. Films **82** and **84** preferably have a thickness in the range of 0.01 to 0.5 mm, and more preferably have a thickness of about 0.05 mm.

[0214] FIG. **20** shows another embodiment of a cartridge for ultrasonically lysing sample components. The cartridge **90** includes beads **94** in its lysing chamber for rupturing the components captured on the solid phase. The cartridge **90** also includes an ultrasonic transducer **92** in the form of a disk coupled to a wall of the chamber. In operation, the transducer **92** transfers ultrasonic energy to the captured sample components to effect lysing. The ultrasonic energy also agitates the beads so that the beads rupture the sample components to effect lysing. Suitable beads for rupturing sample components include polystyrene and silica. The beads may be porous or non-porous and preferably have a diameter in the range of 1 to 200 μ m. As a specific example, the ultrasonic lysis chamber may have a volume capacity of 110 μ L and contain 10 μ L of glass beads.

[0215] Although the embodiments of FIGS. **19** and **20** show cartridges that perform only lysing functions, it is to be understood that the ultrasonic lysis of the present invention may be incorporated into cartridges that perform a variety of other function. For example, referring again to FIG. **2**, an ultrasonic transducer may be coupled to the lysing chamber **119** to lyse cells, spores, or microorganisms in a fluid sample. Further, beads could also be put in the chamber **119** to rupture the sample components. In another embodiment, a heating

element may be used in place of or in combination with an ultrasonic transducer to lyse sample components captured on a solid phase.

[0216] Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention, but merely as illustrations of some of the presently preferred embodiments. Many possible variations and modifications to the invention will be apparent to one skilled in the art upon consideration of this disclosure. Therefore, the scope of the invention should be determined by the following claims and their legal equivalents.

1-53. (canceled)

54. A method for extracting nucleic acid from a sample, the sample containing cells, spores, or microorganisms, the method comprising the steps of:

- a) introducing the sample into a cartridge having:
 - i) a lysing chamber for lysing the cells, spores, or microorganisms to release the nucleic acid therefrom;
 - ii) a capture region containing capture material for capturing the nucleic acid;
 - iii) at least one waste chamber; and
 - iv) at least a third chamber for receiving the nucleic acid extracted from the sample;
- b) contacting the sample with paper or membrane material in the lysing chamber, the paper or membrane material being impregnated with at least one chemical for lysing the cells, spores, or microorganisms in the sample;
- c) lysing the cells, spores, or microorganisms with the chemical to release the nucleic acid from the cells, spores, or microorganisms;
- d) removing the nucleic acid from the lysing chamber by placing fluid in the lysing chamber, releasing the nucleic acid from the paper or membrane material into the fluid, and forcing the fluid containing the nucleic acid to flow out of the lysing chamber and through the capture region, thereby capturing the nucleic acid from the fluid with the capture material in the capture region;
- e) forcing the fluid that has flowed through the capture region to flow into the waste chamber; and
- f) eluting the captured nucleic acid from the capture region and forcing the eluted nucleic acid to flow into the third chamber.

55. The method of claim **54**, the third chamber comprises a reaction chamber, and the method further comprises the steps of:

- i) amplifying the nucleic acid in the reaction chamber; and
- ii) detecting the amplified nucleic acid.

56. The method of claim **55**, wherein the amplification requires temperature control of the reaction chamber, the portion of the cartridge defining the reaction chamber protrudes from the rest of the cartridge body, and the temperature of the reaction chamber is controlled by inserting the reaction chamber into a thermal sleeve and heating or cooling the reaction chamber according to a time/temperature profile.

57. The method of claim **55**, wherein the cartridge further includes a reagent chamber containing dried or lyophilized reagents, and the method further comprises the step of mixing the eluted nucleic acid with the reagents in the reagent chamber prior to forcing the nucleic acid to flow into the reaction chamber.

58. The method of claim **54**, wherein the capture material comprises at least one solid support selected from the group consisting of filters, membranes, beads, fiber, glass wool, filter paper, polymers, and gel.